Genscript Biotech Corporation
金斯瑞生物科技股份有限公司 *
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 1548)

VOLUNTARY ANNOUNCEMENT
RESEARCH AND DEVELOPMENT UPDATE

Reference is made to the voluntary announcement of GenScript Biotech Corporation (the "**Company**", together with its subsidiaries, the "**Group**") dated 28 October 2016, 14 May 2017, 6 June 2017, 1 November 2018, 4 December 2018, 16 April 2019, 7 November 2019, 8 December 2019, 9 December 2019 and 5 November 2020.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that, on 5 December 2020 (New York time), Legend Biotech Corporation ("**Legend Biotech**"), a non-wholly owned subsidiary of the Company, announced the latest data results from the combined Phase 1b/2 CARTITUDE-1 study (NCT03548207) of ciltacabtagene autoleucel (cilta-cel). The data continued to show a very high overall response rate (ORR) that deepened over time, with 97 percent of patients achieving a response and 67 percent of patients achieving a stringent complete response (sCR) at a median follow-up of 12.4 months. The data were presented at the 62nd American Society of Hematology (ASH) Annual Meeting and Exposition (Abstract #177) as an oral presentation.

Cilta-cel is an investigational B-cell maturation antigen (BCMA) directed chimeric antigen receptor T cell ("**CAR-T**") therapy, for the treatment of patients with relapsed or refractory multiple myeloma (RRMM), sponsored by Janssen Research & Development, LLC.

The trial included 97 patients treated with cilta-cel who received a median of six (range, 3–18) prior lines of therapy; 88% (n=85) were triple-refractory, 42% (n=41) were penta-refractory and 99% (n=96) were refractory to the last line of therapy. The median administered dose was 0.71×10^{6} CAR + viable T cells/kg and manufacturing of cilta-cel was successful for all patients. ORR per independent review was 97%, which included a sCR rate of 67%, very good partial response rate (VGPR) of 26% (VGPR or better, 93%) and partial response rate of 4%. Median time to first response was 1 month (range, 0.9–8.5) and responses were ongoing in 72% (n=70) of patients. Of 57 minimal residual disease (MRD) evaluable patients, 93% (n=53) were MRD negative at 10^{-5}. Median progression-free survival (PFS) was not reached at median follow-up of 12.4 months (range, 1.5–24.9). The 12-month PFS rate was 77% (95% confidence interval [CI], 66–84) and the 12-month OS rate was 89% (95% CI, 80–94).

The study also demonstrated a manageable safety profile for cilta-cel at the recommended Phase 2 dose. In the combined results, the most common hematologic adverse events (AEs) observed in the CARTITUDE-1 study were neutropenia (96%); anemia (81%); thrombocytopenia (79%); leukopenia (62%); and lymphopenia (53%). Cytokine release syndrome (CRS) of any grade was observed in 95% of patients, with a median duration of four days (range, 1–97), and 99% of which resolved within 14 days of onset. Of the 92 patients with CRS, most were Grade 1/2 (95%, n=87), 3% were Grade 3 (n=3), 1% was Grade 4 (n=1) and 1% was Grade 5 (n=1). The median onset of CRS was seven days (range, 1–12) post-infusion, with 89% (n=82) of patients experiencing CRS onset at day four or later, which is supportive of potential outpatient administration for cilta-cel. Total CAR-T cell neurotoxicity of any grade was observed in 21% (n=20) of patients, with Grade ≥3 neurotoxicity observed in 10% (n=10) of patients. Of these, Immune effector Cell-Associated Neurotoxicity Syndrome (ICANS) was observed in 16 patients and generally occurred concurrently with CRS; other neurotoxicities were observed in 12 patients and generally occurred after resolution of CRS and/or ICANS (eight patients experienced both ICANS and other neurotoxicities). ICANS events were resolved in all patients with a median time to recovery of four days (range, 1–12). Other neurotoxicities were resolved in six patients at a median time of 75 days (range, 2–160) and were not resolved in six patients (one with ongoing toxicity, one died from neurotoxicity and four died due to other causes). Fourteen deaths were reported during the study: five due to disease progression, three due to adverse events unrelated to treatment (acute myelogenous leukemia [n=2], pneumonia [n=1]) and six due to adverse events related to treatment (sepsis and/or septic shock [n=2], CRS/HLH [n=1], neurotoxicity [n=1], respiratory failure [n=1], and lung abscess [n=1]).

The Group is encouraged by the strong results from the CARTITUDE-1 study showing the potential of its lead product candidate cilta-cel to be a transformative treatment option for patients living with relapsed or refractory multiple myeloma. The Group looks forward to advancing this potentially life-saving treatment approach for patients in need.

For details in relation to CARTITUDE-1, please refer to the voluntary announcement of the Company dated 5 November 2020.

Shareholders and potential investors of the Company are advised to pay attention to investment risks and exercise caution when they deal or contemplate dealing in the securities of the Company.

By Order of the Board
Genscript Biotech Corporation
MENG Jiange
Chairman and Executive Director

Hong Kong, 6 December 2020

As at the date of this announcement, the executive Directors are Mr. Meng Jiange, Ms. Wang Ye and Dr. Zhu Li; the non-executive Directors are Dr. Wang Luquan, Mr. Pan Yuexin and Ms. Wang Jiafen; and the independent non-executive Directors are Mr. Guo Hongxin, Mr. Dai Zumian, Mr. Pan Jiuan and Dr. Wang Xuehai.

* *For identification purposes only*